

SEP - 9 2005

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

K041820
510(k) Summary
for the
ProGuard Lens Case

1. Submitter Information

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097

Contact Person: Steven Dowdley
Telephone No. 678-415-3897

2. Device Name

Classification Name: Soft (hydrophilic) contact lens care products
Proprietary Name: ProGuard Lens Case

3. Predicate Devices

Contact Lens Case (K943183)

4. Description of the Devices

Data indicate that lens cases are a significant source of microbial contamination. The ProGuard Lens Case is a contact lens storage case that is infused with silver to help minimize contamination on the lens case surface. Laboratory testing showed that the silver ions reduce bacterial growth of *Pseudomonas aeruginosa* and *Citrobacter amalonaticus* on the case surface after 24 hours. No significant reduction was observed in the ProGuard lens case with *S. epidermidis*, *S. aureus*, *P. mirabilis* and *S. marcescens* (2 isolates).

5. Indications for Use

The ProGuard Lens Case is indicated for storage of soft (hydrophilic) contact lenses.

6. Description of Safety and Substantial Equivalence

Non-clinical Studies

A series of nonclinical studies were completed to demonstrate the substantial equivalence of the ProGuard Lens Case to the predicate device. All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the lens case is non-toxic and biocompatible, and is comparable to other currently marketed contact lens cases. Results from all tests demonstrate the substantial equivalence of the case to other to previously FDA cleared devices.

Microbiology

Direct Microbial Challenge Studies

In a series of direct microbial challenge studies, ProGuard lens cases and regular lens cases were exposed to saline suspensions of 8 bacteria isolates and incubated at room temperature. After 4 hours there was no difference between the ProGuard lens case and the regular lens cases. After 24 hours the ProGuard lens cases showed significant reduction of 3 of the 8 bacteria isolates tested (*P. aeruginosa* GSU3, *P. aeruginosa* ATCC 9027, *C. amalonaticus*). There was no

significant reduction difference between the ProGuard lens case and the regular lens case for *S. epidermidis*, *S. aureus*, *P. mirabilis* and *S. marcescens* (2 isolates).

AA Determination of Silver in the Lens Case & Lenses

In this study, atomic absorption was used to determine the concentration of silver found in the soaking solution of a ProGuard Lens Case and lenses exposed to the lens case. Under the conditions of the study, the results demonstrated that the average amount of silver found in a lens case cycled with AQUify MPS was approximately 30ppb. Lenses cycled in the same solution demonstrated a silver concentration ranging from 0.001 to 0.010µg/lens.

Cytotoxicity

A series of cytotoxicity studies were conducted to demonstrate the safety and substantial equivalence of the ProGuard Lens Case. Results of the testing demonstrated that the lenses case is non-cytotoxic and is a non-irritant.

USP Elution Test of Extracts of Case and Lid - A Reactivity Grade of zero (0) was observed for components of the ProGuard Lens Case.

USP Direct Contact Test of Extracts of Case and Lid - A Reactivity Grade of zero (0) was observed for the components of the ProGuard Lens Case.

USP Direct Contact with Karats & Test Lens Case (Group I, IV & Silicone Hydrogels) - All lens groups/solution combinations tested produced a Reactivity Grade of zero (0) and exhibited no biological reactivity according to the USP Direct Contact Test.

USP Elution Test of with Karats MPS - A Reactivity Grade of zero (0) was observed for AQUify Multipurpose Solution stored in the ProGuard Lens Case.

ISO Ocular Irritation Test of Lens Case Base – ProGuard Lens Case bases were evaluated according to ISO 10993-10 for ocular irritation in the rabbit using saline and cottonseed oil extracts. Ocular scores were negative for all test and control eyes at 1, 24, 48 and 72 hours.

ISO Ocular Irritation Test of Aqua Lens Case Caps - ProGuard Lens Case caps were evaluated according to ISO 10993-10 for ocular irritation in the rabbit using saline and cottonseed oil extracts. Ocular scores were negative for all test and control eyes at 1, 24, 48 and 72 hours.

ISO Ocular Irritation Test of White Lens Case Caps - ProGuard Lens Case caps were evaluated according to ISO 10993-10 for ocular irritation in the rabbit using saline and cottonseed oil extracts. Ocular scores were negative for all test and control eyes at 1, 24, 48 and 72 hours.

Systemic Toxicity of Test Extracts of Lens Case Base - ProGuard Lens Case bases were evaluated according to USP and ISO 10993-11 for systemic toxicity in the mouse, using saline and cottonseed oil extracts. No evidence of systemic toxicity was observed.

Systemic Toxicity of Test Extracts of Aqua Lens Case Caps - ProGuard Lens Case caps were evaluated according to USP and ISO 10993-11 for systemic toxicity in the mouse, using saline and cottonseed oil extracts. No evidence of systemic toxicity was observed.

Systemic Toxicity of Test Extracts of White Lens Case Caps - ProGuard Lens Case caps were evaluated according to USP and ISO 10993-11 for systemic toxicity in the mouse, using saline and cottonseed oil extracts. No evidence of systemic toxicity was observed.

Clinical Study

Two clinical studies were conducted to evaluate the performance of the ProGuard Lens Case versus a standard control lens case.

Clinical Study #1

This study was one month clinical trial with 39 subjects using AQuify MPS. Each subject in the trial used one bowl of a ProGuard Lens Case and one bowl of a control case to store their lenses. For the control lens cases, after disinfection, subjects were instructed follow the case care instructions for the control case (e.g., empty the solution, rinse with fresh AQuify MPS and leave open to air dry). For the test case, the subjects followed one of the following case care regimen:

Test Case Regimen 1 - the case was emptied rinse with AQuify MPS, then re-capped

Test Case Regimen 2 - the case was emptied, rinse and re-filled with fresh AQuify MPS.

At the conclusion of the study, the ProGuard Lens Cases had a statistically significantly lower degree of bacterial contamination than the control lens cases – 26% (test case) versus 67% (control case). This study also demonstrated that recapping the ProGuard Lens Case did not cause an increase the microbial contamination of the case.

Clinical Study #2

This study was a one month clinical trial with 40 subjects using AQuify MPS with their lenses stored in one bowl of the ProGuard Lens Case and one bowl of the control lens case. After disinfection, the subjects were instructed to empty the cases, rinse with AQuify MPS and then re-cap the cases. In this study, the ProGuard Lens Cases had a statistically significantly lower degree of bacterial contamination than the control lens cases – 38% (test case) versus 63% (control case).

7. Substantial Equivalence

The data provided in this 510(k) submission concludes that the ProGuard Lens Case is substantially equivalent to the predicate lens case for storage of soft (hydrophilic contact lenses).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jerry Land, O.D.
Head, Regulatory Affairs - Americas
Global Clinical and Regulatory Affairs
CIBA Vision Corp.
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K041820
Trade/Device Name: ProGuard™ Lens Case
Regulation Number: CFR886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: II
Product Code: LRX
Dated: September 9, 2005
Received: July 19, 2004

Dear Dr. Land:

This letter corrects our substantially equivalent letter of September 9, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "Malvina B. Eydelman, M.D." with a stylized flourish at the end.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K041820

Device Name: ProGuard™ Lens Case

Indications For Use:

The ProGuard™ Lens Case is indicated for storage of soft (hydrophilic) contact lenses with AQuify® Multipurpose Solution.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Quynh Hoang
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K041820